

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

19 FEDERAL REPUBLIC
OF GERMANY

12 **Off nl gungsschrift**
[Laid-open Application]

11 **DE 39 30 451 A1**

51 Int. Cl.⁵:
A 61 B 17/39
A 61 B 5/05
A 61 B 5/02
A 61 B 5/03

GERMAN
PATENT AND
TRADEMARK OFFICE

21 Serial No.: P 39 30 451.5
22 Application date: 12 September 1989
43 Date laid open: 21 March 1991

71 Applicant:
Fischer MET GmbH, 7800 Freiburg, DE

74 Agent:
Wuesthoff, F., Dr.-Ing.; Frhr. von Pachmann,
E., Dipl.-Chem. Dr.rer.nat.; Behrens, D., Dr.-
Ing.; Goetz, R., Dipl.-Ing. Dipl.-Wirtsch.-Ing.;
Hellfeld von, A., Dipl.-Phys. Dr.rer.nat., Patent
Attorneys, 8000 Munich

72 Inventor:
Hoffmann, Ellen, Dr. med.; Steinbeck, Gerhard,
Prof. Dr. med., 8000 Munich, DE; Mattmüller,
Rudi, Ing. (graduated), 7800 Freiburg, DE

54 Device for high-frequency coagulation of biological tissue

A device for high-frequency coagulation of biological tissue achieves readily controllable and uniform coagulation even of very inhomogeneous tissue. For this purpose one front and one rear electrode (5, 8), which are each at least partly cylindrical and are disposed one after the other in the direction of a common longitudinal axis (9), are dimensioned such that the dimension (d_1) of a front electrode (8) is smaller than the dimension (d_2) of a rear electrode (5).

[see original for Fig. 2]

- 2 -

Specification

The invention relates to a device for high-frequency coagulation of biological tissue, with at least one front and one rear electrode, which are each at least partly cylindrical and are disposed one after the other in the direction of a common longitudinal axis and are also provided with uncovered outside faces, which have different dimensions in the direction of the longitudinal axis.

Such devices are known from US Patent 3920021 and European Patent 0040138.

The bipolar coagulation instrument described in US Patent 3920021 is provided with two coaxial cylindrical electrodes, although the rear electrode has smaller dimension in the direction of the common longitudinal axis of the instrument than does the front electrode.

The object of the present invention is to provide, for high-frequency coagulation of biological tissue, a device that is suitable in particular for surgical correction of cardiac rhythm disorders.

The invention is based on the knowledge that very good coagulation results are achieved when, in a device of the type cited in the introduction, the dimension of the front electrode is smaller than that of the rear electrode.

Diverse studies on living tissue have shown that, in the case of symmetric arrangement of bipolar electrode faces (or in other words electrodes whose outside faces have identical dimensions within the aforesaid meaning), the coagulated matter preferably forms between the equally large electrode faces. In such a symmetric arrangement of the electrodes, variations in the tissue structure or in the blood supply to the tissue lead to hardly any shift of the position of the coagulated matter out of the region between the electrode faces.

In the case of electrode faces having an extremely asymmetric configuration (or in other words an extreme difference between the dimensions of the electrode faces), the coagulated tissue grows spherically around the smaller front electrode, similarly to the case of a monopolar electrode. If the front electrode face of such an arrangement is located in a tissue zone with inhomogeneous conductivity, the high-frequency field propagates in a manner that cannot be exactly controlled. In this respect, an arrangement of extremely asymmetric electrodes is similar to a pure monopolar arrangement in which a relatively large second electrode is formed by a "neutral electrode".

The inventive knowledge that what is important is the dimensions of the electrodes and in particular the ratio of these dimensions makes it possible to achieve exactly controlled coagulation results in tissue structures having highly inhomogeneous properties. In other words, the formation of the coagulated matter can be controlled as desired.

In a preferred embodiment of the inventive device, it is provided that the ratio of the dimensions of the front and rear electrodes ranges between 5:6 and 1:5.

The front electrode is 5 to 50%, preferably 10 to 30% shorter than the rear electrode. In the case of curved geometry of the electrodes, especially of the front electrode, the word "dimension" is to be understood as the projection of the outside face of the electrodes on a line parallel to the longitudinal axis of the elongate coagulation device.

It has been surprisingly found that, if the dimensions of the electrodes are configured according to the invention, a path of the HF field lines is achieved that leads to uniform and readily controllable coagulation even under inhomogeneous conditions in the surroundings of the electrodes. The lesion can be controlled and confined very readily. This is true in particular for applications on the living beating heart, wherein the instrument is located in the blood and the front electrode presses against the cardiac tissue. When coagulation is attempted with a symmetric electrode arrangement (meaning equal dimensions of the electrodes), a lesion is hardly perceptible in the cardiac tissue. Instead, dangerous blood clots form at the electrode face located in the blood. On the other hand, if the electrode arrangement is too asymmetric, the coagulation focus becomes uncontrollably spread out due to the great differences between the conductivities of blood and tissue.

It is only in an inventive and therefore slightly asymmetric arrangement of the electrodes that the coagulation focus remains close to the electrodes. In this connection, the coagulation is temperature-controlled in a manner known in itself. In a preferred embodiment of the invention, a temperature sensor is embedded in the front electrode for this purpose.

According to another preferred embodiment of the inventive device, it is provided that more than two electrode faces are disposed in the front region of the instrument. Coagulation can then be achieved selectively between selected electrode faces.

Another embodiment of the invention provides that different high-frequency energies are delivered simultaneously or successively to the individual electrode faces. Thereby it is possible

- 4 -

to distribute the high-frequency energy in the tissue in a manner that can be systematically calculated.

According to another version, the invention provides that the electrode faces are used not only for coagulation but also as measuring sensors for determining the impedance of the surrounding tissue.

According to another modification, the invention provides that the different electrode faces are used not only for coagulation but also as measuring sensors for determining the spatial distribution of the high-frequency energy and for controlling the spread of coagulation.

According to another embodiment, which can also be used independently of the other features of the invention, it is provided that a pressure sensor known as such is disposed in the tip of the coagulation instrument in order to be able to detect different tissue structures. With such a pressure sensor, it is also possible to measure pressures, especially fluid pressures, before and during and after coagulation.

According to a preferred embodiment of this practical example of the invention, the pressure sensor is disposed in such a way in the tip of the coagulation instrument that it is sensitive to direction and can therefore be used to determine the location of the electrodes.

A practical example of the invention is explained in more detail hereinafter on the basis of the drawing, wherein:

Fig. 1 shows a schematic diagram of a device for high-frequency coagulation, and

Fig. 2 shows detail A of the device according to Fig. 1 on larger scale.

The device shown in the figures is a heart catheter, which comprises a highly elastic steel spring coated with extremely elastic plastic.

A metal bush (1) contains microelectronic devices for digital coding of the instrument type being used and for storage of the physical properties of the instrument. The device is connected by means of a plug connector (2) to a high-frequency generator known as such. It is presumed here that the principles of high-frequency coagulation and control thereof are known.

Fig. 2 shows detail A of Fig. 1 and the inventive configuration of the tip of the coagulation device.

A helical spring (3) of spring steel supports and guides the electrodes. Helical spring (3) is coated externally by insulating material (3'), so that lead (5') for a rear electrode (5) is

- 5 -

electrically isolated from helical spring (3). As shown in Fig. 2, an insulating jacket (4) of insulating plastic is disposed on the outside of lead (5').

As is evident from Fig. 2, all illustrated components of the coagulation device are rotationally symmetric with respect to a longitudinal axis (9). Toward the distal end of the device, a ring (6) of electrically insulating material (plastic) adjoins rear electrode (5). At the distal end of the device, a front electrode (8) adjoins ring (6). The outside faces of rear electrode (5), of insulating ring (6) and of rear electrode (8) adjoin one another in a flush, continuous arrangement. The outside faces (10, 11) of the front and rear electrodes (8) and (5) respectively, being uncovered and thus coming into contact with the tissue, etc., are cylindrical and coaxial and, outside a bent portion (10') of front electrode (8), have identical diameters.

In Fig. 2, the dimensions (d_1) of front electrode (8), (d_3) of insulating ring (6) and (d_2) of rear electrode (5) are illustrated together with examples of their values in millimeters. In the illustrated practical example, the dimension (d_1) of front electrode (8) in the direction of longitudinal axis (9) is 3 mm, whereas the corresponding dimension (d_2) of rear electrode (5) is 4 mm. The ratio of the dimensions is therefore 3:4. The dimension (d_3) of insulating ring (6) in the direction of longitudinal axis (9) corresponds to the dimension (d_1) of front electrode (8).

The dimension (d_3) of the insulating ring corresponds preferably to the dimension (d_1) of front electrode (8) with a variation of $\pm 25\%$.

An NiCr-Ni thermocouple (7) fastened by means of a cement having very good thermal conductivity is disposed exactly at the center of front electrode (8). Thermocouple (7) is used for temperature control of the coagulation process.

Claims

1. A device for high-frequency coagulation of biological tissue, with at least one front (8) and one rear electrode (5), which are each at least partly cylindrical and are disposed one after the other in the direction of a common longitudinal axis (9) and are also provided with uncovered outside faces (10, 11), which have different dimensions (d_1 , d_2) in the direction of the longitudinal axis (9), characterized in that the dimension (d_1) of the front electrode (8) is smaller than the dimension (d_2) of the rear electrode (5).

- 6 -

2. A device according to claim 1, characterized in that the ratio of the dimensions of the front and rear electrodes ranges between 5:6 and 1:5.
3. A device according to one of claims 1 or 2, characterized in that a temperature sensor (7) is disposed in the front electrode between the outside faces (10) thereof.
4. A device according to one of the preceding claims, characterized in that more than two electrode faces are disposed in the front region of the device, and coagulation is provided selectively between different electrode faces.
5. A device according to one of the preceding claims, characterized in that different high-frequency energies can be transmitted simultaneously or successively to the individual electrode faces.
6. A device according to one of the preceding claims, characterized in that the electrode faces (10, 11) are provided as measuring sensors for determining the tissue impedance.
7. A device according to one of the preceding claims, characterized in that the electrode faces (10, 11) are used as measuring sensors for determining a high-frequency distribution and for monitoring the spread of coagulation.
8. A device according to one of the preceding claims, characterized in that a pressure sensor disposed in the front region of the device.
9. A device according to one of the preceding claims, characterized in that a directionally dependent pressure sensor is disposed in the tip of the device.

Attached hereto: 1 page of drawings

- 7 -

DRAWINGS PAGE 1

Number: DE 39 30 451 A1
Int. Cl.³: A 61 B 17/39
Date laid open: 21 March 1991

[see original for drawing]